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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,152	02/01/2001	Chris C. Miller	RR-473PCT/US	1414

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 08/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/762,152

Applicant(s)

MILLER, CHRIS C.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-13,15-18,31-41 and 56-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,19-30 and 42-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-13,15-18,31-41 and 56-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 02 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 14, 19-30, 42-55) in Paper No. 9 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42-55 provide for the use of nitric oxide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 42-55 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

Claims 23, 27, 30, 51 and 55 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. All mentioned claims recite "...wherein the animal is a human". All parent claims already include this recitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 19-23 and 42-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al (WO 9509612).

Green teaches compositions capable of releasing nitric oxide and therapeutic methods of use thereof for the treatment of microorganism-related disease states. It is disclosed that direct delivery of nitric oxide gas kills intracellular pathogens such as *Mycobacterium tuberculosis*. An ability to specifically deliver compounds capable of releasing nitric oxide to the desired site of infection within the macrophage would greatly enhance killing of intracellular pathogens (page 5, lines 6-13).

Green discloses a method of inhibiting the proliferation of parasites, fungi, bacteria and other proliferating cells or organisms (page 7, lines 30-34). Also disclosed is that the nitric oxide releasing compounds, alone or in combination with other suitable components, can be made into aerosol formulations to be administered via inhalation (page 23, lines 7-10). Administration through the aerosol route is highly beneficial to humans or animals with pulmonary infections. Various bacterial, protozoan, fungal, viral and parasitic infections of the respiratory system that involve macrophages are attacked in this fashion (page 29, lines 15-25).

Green discloses that the dose administered to an animal, particularly a human, should be sufficient to effect a therapeutic response in the animal over reasonable time frame (page 24, line 30 to page 24, line 12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-30, 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (WO 9509612) in view of Blaise (WO 9801142).

Green, discussed above, while disclosing general teachings on the dosage and therapeutic time frame, lacks specific disclosure on the concentration of nitric oxide.

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Blaise discloses the use of nitric oxide as a gaseous drug for preventing or controlling inflammatory response following extracorporeal blood circulation in humans and animals. The gaseous drug is preferably inhaled and delivered to a human or animal by oral or nasal intubation, during at least part of the pre-operative preparation period, during the operation and during part of the post-operative recovery period. The drug is preferably administered at a concentration of 0.5 to 80 ppm. The use of nitric oxide is also intended to protect the renal, pulmonary, hepatic and neurological functions following extracorporeal blood circulation (abstract and page 7, lines 6-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings of Green et al on methods of treating pulmonary infections caused by pathogens using an effective amount of nitric oxide administered directly to the desired site to have looked in the art for a specific concentration of nitric oxide as disclosed by Blaise with the reasonable expectations of successfully preparing a formulation of nitric oxide that is both safe and effective for treatments of disorders such as respiratory tract infection.

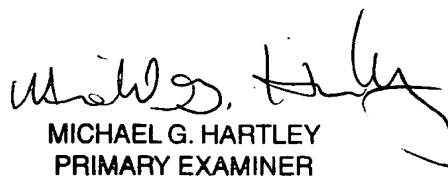
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghghatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
August 27, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER